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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,102	06/20/2000	Christopher Graham Raphael Parsons	MERZ30 / dln	6038

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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,102	PARSONS ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment submitted on June 9, 2006. Claims 1-13 and 15-17 are pending in the application, and are being examined on the merits herein.

The rejection of the claims under 35 U.S.C. 103(a) over Gold et al. in view of Lucot et al. is being withdrawn in view of Applicant's amendments to the claims to delete the treatment of the disorder that is emesis. Gold et al. and Lucot et al. do not teach or suggest the treatment of the specific conditions that are cerebellar tremor, appetite disorders and irritable bowel syndrome, as recited in the newly amended claims.

The claims are being newly rejected as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/01416 to Gold et al, in view of WO 99/55323 to Asghar et al, published November 4, 1999.

Gold et al. teaches that 1-aminocyclohexane act as NMDA receptor antagonists, (see abstract, in particular), and teaches that the NMDA receptor antagonist 1-aminocyclohexanes include those as instantly recited in claims 1-13 and 15 (see pages 3-8, in particular.) Gold et al. teaches that the compounds can be provided for the treatment of conditions that are alleviated by NMDA receptor antagonists (see abstract, in particular), and teaches that the compounds can be provided in combination with pharmaceutically acceptable diluents, excipients or carriers (see page 6, in particular), as recited in claims 16-17.

Gold et al. does not teach that the compounds can be provided to treat the specific conditions of cerebellar tremor, appetite disorders and irritable bowel syndrome, as recited in the instant claims.

Asghar et al. teaches that pharmaceutical compounds having NMDA antagonist activity are suitable for the treatment of certain conditions of the gastrointestinal tract, such as irritable bowl syndrome (IBS) (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the compounds of Gold et al. in the treatment of IBS as taught by Asghar et al, because Gold et al. teaches that the instantly claimed compounds are NMDA receptor antagonists, while Asghar et al. teaches that NMDA receptor antagonists are effective in the treatment of IBS. Thus, one of ordinary skill in the art would have been motivated to provide compound of Gold et al. to a patient with IBS, with the expectation of providing a compound capable of treating the IBS.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/01416 to Gold et al, in view of the article entitled "The Treatment of Heroin Addicts with Dextromethorphan: A Double-Blind Comparison of Dextromethorphan with Chlorpromazine" by Koyuncuoglu et al, 1990, International Journal of Clinical Pharmacology, Therapy and Toxicology, vol. 28, no. 4, pages 147-152.

Gold et al. teaches that 1-aminocyclohexane act as NMDA receptor antagonists, (see abstract, in particular), and teaches that the NMDA receptor antagonist 1-aminocyclohexanes include those as instantly recited in claims 1-13 and 15 (see pages 3-8, in particular.) Gold et al. teaches that the compounds can be provided for the treatment of conditions that are alleviated by NMDA receptor antagonists (see abstract, in particular), and teaches that the compounds can be provided in combination with pharmaceutically acceptable diluents, excipients or carriers (see page 6, in particular), as recited in claims 16-17.

Gold et al. does not teach that the compounds can be provided to treat the specific conditions of cerebellar tremor, appetite disorders and irritable bowel syndrome, as recited in the instant claims.

Koyuncuoglu et al. teaches that NMDA antagonists appear very promising for the treatment of opiate addicts, and provides comparative results for a conventional drug withdrawal treatment combination (CPZ+DIA) versus a treatment containing the NMDA receptor antagonist that is dextromethorphan (DM+DIA) (see abstract, in particular.) Koyuncuoglu et al. teaches that the treatment containing the NMDA receptor antagonist reduced the intensity of various symptoms of withdrawal, including anorexia (see abstract and paragraph bridging pages 149-150, in particular.) Thus, Koyuncuoglu et

al. teaches that NMDA receptor antagonists can be provided to treat the symptoms of heroin withdrawal, and including anorexia.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the compounds of Gold et al. in the treatment of symptoms of heroin withdrawal, such as anorexia, as taught by Koyuncuoglu et al, because Gold et al. teaches that the instantly claimed compounds are NMDA receptor antagonists, while Koyuncuoglu et al. teaches that NMDA receptor antagonists are effective in the treatment of the symptoms of heroin withdrawal such as anorexia. Thus, one of ordinary skill in the art would have been motivated to provide compound of Gold et al. to a patient experiencing anorexia as a symptom of heroin withdrawal, with the expectation of providing a compound capable of treating the condition.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/01416 to Gold et al, in view of the article entitled "Classification of Tremor and Update on Treatment" by Charles et al, 1999, American Family Physician, volume 59, number 6, pages 1565-1572.

Gold et al. teaches that 1-aminocyclohexane act as NMDA receptor antagonists, (see abstract, in particular), and teaches that the NMDA receptor antagonist 1-aminocyclohexanes include those as instantly recited in claims 1-13 and 15 (see pages 3-8, in particular.) Gold et al. teaches that the compounds can be provided for the

treatment of conditions that are alleviated by NMDA receptor antagonists (see abstract, in particular), and teaches that the compounds can be provided in combination with pharmaceutically acceptable diluents, excipients or carriers (see page 6, in particular), as recited in claims 16-17.

Gold et al. also teaches that the NMDA receptor antagonists can be provided for the treatment of chronic neurodegenerative disorders such as multiple sclerosis (see paragraph bridging pages 46-47, in particular.)

Gold et al. does not teach that the compounds can be provided to treat the specific conditions of cerebellar tremor, appetite disorders and irritable bowel syndrome, as recited in the instant claims.

Charles et al. teaches that cerebellar tremors are due to lesions of the cerebellar hemisphere and related areas (see page 1567, first full paragraph of right hand column , in particular.) Charles et al. teaches that the most common cause of cerebellar tremor is multiple sclerosis (see page 1568, left hand column, first full paragraph, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the compounds of Gold et al. in the treatment of cerebellar tremor resulting form multiple sclerosis, as taught by Charles et al, because Gold et al. teaches that the instantly claimed compounds are capable of treating

neurodegenerative disorders such as multiple sclerosis, while Charles et al. teaches that cerebellar tremor is most commonly caused by multiple sclerosis. Thus, one of ordinary skill in the art would have been motivated to provide compound of Gold et al. to a patient experiencing cerebellar tremor as a symptom of multiple sclerosis, with the expectation of providing a suitable treatment for the multiple sclerosis.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/01416 to Gold et al, in view of EP 427518 to Kloog et al, published May 15, 1991, and further in view of the article entitled "Classification of Tremor and Update on Treatment" by Charles et al, 1999, American Family Physician, volume 59, number 6, pages 1565-1572.

Gold et al. teaches that 1-aminocyclohexane act as NMDA receptor antagonists, (see abstract, in particular), and teaches that the NMDA receptor antagonist 1-aminocyclohexanes include those as instantly recited in claims 1-13 and 15 (see pages 3-8, in particular.) Gold et al. teaches that the compounds can be provided for the treatment of conditions that are alleviated by NMDA receptor antagonists (see abstract, in particular), and teaches that the compounds can be provided in combination with pharmaceutically acceptable diluents, excipients or carriers (see page 6, in particular), as recited in claims 16-17.

Gold et al. does not teach that the compounds can be provided to treat the specific conditions of cerebellar tremor, appetite disorders and irritable bowel syndrome, as recited in the instant claims.

Kloog et al. teaches that NMDA receptor antagonists are effective at alleviating and even preventing glutamate neurotoxicity due to central nervous system injuries, such as seizures or compromised or reduced blood supply, and including stroke (see page 2, lines 1-15 and 40-50, in particular.)

Gold et al. and Kloog et al. do not specifically teach providing the NMDA antagonists for the treatment of the specific conditions recited, such as cerebellar tremor.

Charles et al. teaches that cerebellar tremors are due to lesions of the cerebellar hemisphere and related areas (see page 1567, first full paragraph of right hand column , in particular.) Charles et al. teaches that causes of cerebellar tremor include tumors and strokes (see page 1568, left hand column, first full paragraph, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the compounds of Gold et al. in the treatment of cerebellar tremor resulting from stroke, as taught by Kloog et al. and Charles et al, because Gold et al. teaches that the instantly claimed compounds are NMDA receptor

antagonists, while Kloog et al. teaches that NMDA antagonists are capable of treating and alleviating neuronal injury from stroke, and Charles et al. teaches that cerebellar tremor results from neuronal injury, such as that due to stroke. Thus, one of ordinary skill in the art would have been motivated to provide compound of Gold et al. to a patient experiencing cerebellar tremor as a symptom of stroke, with the expectation of providing a suitable treatment for the stroke.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 16-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 6,828,462 to Henrich et al, issued December 7, 2004, in view of WO 99/01416 to Gold et al, and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al, as discussed above.

The claims are not patentably distinct from one another because the patented claims are to the same general chemical formula of 1-aminocyclohexanes as that instantly claimed, and claims the compounds for the treatment of conditions treatable by NMDA receptor antagonists. Gold et al. teaches the specific compounds as instantly claimed by Applicants that meet the general formula as claimed in the patented case, and teaches their use as NMDA receptor antagonists. The references (1), (2), (3) and (4), together with Gold et al, teach providing the NMDA receptor antagonists for the treatment of the instantly claimed conditions, as has been discussed above. Accordingly, it would be obvious to one of ordinary skill in the art to modify the patented method with the specific compounds of Gold et al. that meet the structural limitations of the more general patented compounds, and provide them for the treatment of the conditions as taught in the prior art, with the expectation of providing methods suitable for the treatment of the conditions. Accordingly, claims 1-13 and 16-17 are not patentably distinct from claims 2 and 4 of Henrich et al, in view Gold et al, and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al.

Claims 1-13 and 16-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 23-36 of U.S. Patent No. 6,034,134 to Gold et al, issued March 7, 2000, in view of WO 99/01416 to Gold et al (hereinafter WO Gold et al), and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al, as discussed above.

The claims are not patentably distinct from one another because the patented claims are to the same general chemical formula of 1-aminocyclohexanes as that instantly claimed, and claims the compounds for the treatment of conditions treatable by NMDA receptor antagonists. WO Gold et al. teaches the specific compounds as instantly claimed by Applicants that meet the general formula as claimed in the patented case, and teaches their use as NMDA receptor antagonists. The references (1), (2), (3) and (4), together with WO Gold et al, teach providing the NMDA receptor antagonists for the treatment of the instantly claimed conditions, as has been discussed above. Accordingly, it would be obvious to one of ordinary skill in the art to modify the patented method with the specific compounds of WO Gold et al. that meet the structural limitations of the more general patented compounds, and provide them for the treatment of the conditions as taught in the prior art, with the expectation of providing methods suitable for the treatment of the conditions. Accordingly, claims 1-13 and 16-17 are not patentably distinct from claims 1-11 and 23-36 of the Gold et al. patent, in view of WO

Gold et al, and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al.

Claims 1-13 and 16-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,071,966 to Gold et al, issued June 6, 2000, in view of WO 99/01416 to Gold et al (hereinafter WO Gold et al), and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al, as discussed above.

The claims are not patentably distinct from one another because the patented claims are to the same general chemical formula of 1-aminocyclohexanes as that instantly claimed, and claims the compounds for the treatment of conditions treatable by NMDA receptor antagonists. WO Gold et al. teaches the specific compounds as instantly claimed by Applicants that meet the general formula as claimed in the patented case, and teaches their use as NMDA receptor antagonists. The references (1), (2), (3) and (4), together with WO Gold et al, teach providing the NMDA receptor antagonists for the treatment of the instantly claimed conditions, as has been discussed above. Accordingly, it would be obvious to one of ordinary skill in the art to modify the patented method with the specific compounds of WO Gold et al. that meet the structural limitations of the more general patented compounds, and provide them for the treatment of the conditions as taught in the prior art, with the expectation of providing methods

suitable for the treatment of the conditions. Accordingly, claims 1-13 and 16-17 are not patentably distinct from claims 1-12 of the Gold et al. patent, in view of WO Gold et al, and further in view of either (1) Asghar et al, (2) Koyuncuoglu et al, (3) Charles et al, or (4) Kloog et al. and Charles et al.

Response to Arguments

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

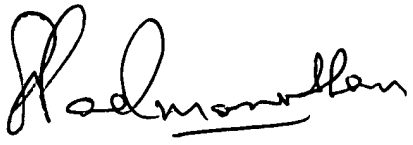
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,728,728 to Water E. Kosachuk teaches that NMDA receptor antagonists can be provided for the treatment of multiple sclerosis (see column 8, lines 10-20, in particular.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



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